IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

IN RE: ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	**Master File No. 2:12-MD-02327** **MDL 2327**
THIS DOCUMENT RELATES TO ALL CASES	**JOSEPH R. GOODWIN** **U.S. DISTRICT JUDGE**

SECOND AMENDED NOTICE TO TAKE ORAL DEPOSITION
OF DEFENDANT ETHICON LLC THROUGH DESIGNATED WITNESS(ES)

TO: Defendant ETHICON, LLC and its Attorneys of Record.

Please take notice that pursuant to Rule 30(b)(6) of the Federal Rules of Civil Procedure, Plaintiffs, by and through their counsel, will take the videotaped deposition of a designated witness or witnesses of Defendant Ethicon, LLC to begin on July 08, 2014, at 9:00 a.m., at the offices of Riker Danzig at One Speedwell Avenue in Morristown, New Jersey. The witness(es) shall be prepared to testify concerning the subject matters identified in Exhibit "A", attached hereto. The witness(es) shall produce documents identified in Exhibit "B", attached hereto, prior to the deposition. The deposition will be taken before a person authorized by law to administer oaths, pursuant to Rule 28 of the Federal Rules of Civil Procedure, and will continue day-to-day until the examination is completed.

DEFINITIONS AND INSTRUCTIONS

All definitions and rules or instructions set forth in Fed. Rule Civ. P. 30(b)(6) shall apply to all requests for information herein. To the extent a term commonly in use in the medical device industry is not defined herein, it shall be understood to be consistent with the meaning

commonly ascribed to that term in the medical device industry.

1. "Concerning" means referring to, describing, evidencing, or constituting. See LR Civ. P 26.2(c)(7).

2. "Defendant", "Ethicon, LLC", "you" or "your" refers to, without limitation, Ethicon, LLC and all business entities with which it is or has been affiliated, together with any predecessor, successor, parent, or subsidiary entity as well as any officer, director, employee, attorney, agent, or representative of any such other business entity previously described herein.

3. "Document" is synonymous in meaning and equal in scope to the usage of this term in Rule 34(a) of the Federal Rules of Civil Procedure and expressly includes writings, drawings, graphs, charts, photographs, sound recordings, images, and other data or data compilations stored in any medium from which information can be obtained either directly or, if necessary, after translation by you into a reasonably usable form. A draft or non-identical copy is a separate document. *See* LR Civ. P. 26.2(c)(2); *see also* FR Civ. P 34(a).

4. "Communication" means every manner or means of disclosure or exchange of information, regardless of means utilized, whether oral, written, electronic, or by document or otherwise, and whether face-to-face, in a meeting, by telephone, mail, telex, discussion, release, personal delivery, or otherwise. Documents that typically reflect a "communication" include letters, electronic-mail, instant messages, handwritten notes, call logs, telephone memoranda, slips, daily appointment books and diaries, bills, checks, correspondence, and memoranda, and includes all drafts of such documents.

5. "Person" means any natural or artificial person, including business entities and other legal entities.

6. "And" or "or" shall be construed conjunctively or disjunctively as necessary to

make the requests inclusive rather than exclusive. The use of the word "including" shall be construed to mean "without limitation."

7. Reference to the singular in any of these requests shall also include a reference to the plural, and reference to the plural shall include a reference to the singular.

8. "Related to" or "relating to" shall mean directly or indirectly supporting, evidencing, describing, mentioning, alluding to, referring to, contradicting, comprising or concerning.

9. All documents should be produced which are not subject to an objection and are known by, possessed or controlled by, or available to you, or your attorneys, representatives, or other agents.

10. All documents are to be produced in their entirety, without abbreviation or redaction, including both front and back thereof, and all attachments or other matters affixed thereto.

11. These requests shall be deemed continuing so as to require further and supplemental production by you in the event you obtain or discover additional documents between the time of responding to this subpoena and the time of any hearing or trial.

12. “Mesh Product” or “Mesh Products” means any product(s) that you developed, designed, distributed, licensed, manufactured, marketed or sold for the treatment of Pelvic Organ Prolapse, (POP)Stress Urinary Incontinence, (SUI) hernia repair, or general surgery.

13. “Relevant Time Period” means the time period from when you first developed, designed, distributed, licensed, manufactured, marketed or sold mesh products to the present.

14. You are to produce all responsive documents to the undersigned counsel no later than 10 days before the deposition.

This 30th Day of May, 2014.

PLAINTIFFS' CO-LEAD COUNSEL

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EXHIBIT "A"

DEPOSITION SUBJECT MATTER

Pursuant to Rule 30(b)(6), the deponent(s) must have knowledge and shall be able to testify concerning the following subject matters:

I. ETHICON LLC COMPANY STRUCTURE AND ORGANIZATION

1. Ethicon, LLC's internal company structure and organization, and more specifically:

   a. The internal organizational structure of Ethicon, LLC's individual departments, groups, divisions, committees and/or task forces;

   b. The organizational structure within each of Ethicon LLC's departments, groups, divisions, and/or committees, including the identity of the individuals who performed supervisory work related to your mesh products;

   c. The identity of all supervisory personnel, involved in the research, development, production, regulatory compliance, testing, packaging, distribution, sanitization, manufacturing and quality control of Ethicon LLC's mesh products ; including identification of department(s) and/or committee(s), said supervisory personnel are assigned to and/or serve on; and

   d. The functions, duties and responsibilities of each department, group, division, and/or committee related to the manufacturing of your mesh products; and

   e. The members of Ethicon, LLC.

2. The nature, location, storage and organization of all documents and electronically stored information related to any activities of Ethicon LLC, including any activities of its boards of directors and/or board of director committees and subcommittees, meeting minutes, reports, handouts and investigational documents from the date Ethicon, LLC first started manufacturing its mesh products (including but not limited to any of their component parts or materials used in the manufacturing process) until the present.

3. The contractual relationship and the contracts with any and all vendors, suppliers or other third parties related to the supply of materials or component parts for the manufacture of the mesh products or in any way related to the manufacture of the mesh products.

4. The structure of any working or functional department or group, committee, and/or task force including the identity of those individuals responsible for tracking, recording, reporting, handling, or following up on complaints, adverse events or other non-conformance issues or problems related to the manufacture of the mesh products.

5. Ethicon LLC's contract(s) and relationships with Medical Device and Diagnostics Global Services, LLC, including all aspects of the agreement and each parties' duties and responsibilities pursuant to the agreement.

6. The company organization and structure of Ethicon LLC relating to the approval, management, administration, operation and compliance with any and all U.S. medical device regulations or standards applicable to your mesh products from the date Ethicon LLC first started developing Mesh Products until the present.

7. The company organization and structure of Ethicon LLC relating to the approval, management, administration, operation and compliance with any and all foreign medical device regulations or standards applicable to your mesh products from the date Ethicon LLC first started developing mesh products until the present.

II. MANUFACTURING AND DISTRIBUTION PRACTICES

1. The following manufacturing topics and the identity of all supervisory persons within Ethicon, LLC and all committees, groups, departments, and/or boards and the like (including their names, responsibilities, dates of operation and the identity of their members),

who/which were responsible at any and all time periods for the following from the date Ethicon, LLC first started manufacturing and distributing its Mesh Products until the present:

a. All raw materials, including additives, that are contained in the polypropylene mesh used in your mesh products and polypropylene sutures, including the suppliers of all such products;

b. The identity of all mesh products and polypropylene sutures manufactured by Ethicon LLC, either in whole or in part, and including a description of the activities performed by Ethicon LLC with regard to each product;

c. The existence and handling of manufacturing related complaints and non-conformance reports for your mesh products and polypropylene sutures;

d. Sterilization and sanitization of the product, plant and equipment used in the manufacture of the mesh products, including those responsible for developing policies and procedures regarding sterilization and sanitization and those responsible for ensuring compliance with those policies and procedures;

e. The maintenance of records regarding the sterilization and sanitization of the mesh products, plant and equipment used in the manufacture of the mesh products, including maintaining and updating policies and procedures regarding sterilization and sanitization;

f. The specifications for all materials and/or component parts that make up your mesh products and polypropylene sutures;

g. Inspecting, measuring, testing, and otherwise ensuring compliance with specifications for finished mesh products and sutures;

h. Inspecting, measuring, testing, and otherwise ensuring compliance with specifications for mesh product components;

i. Inspecting, measuring, testing, and otherwise ensuring compliance with specifications for product raw materials of your mesh products and polypropylene sutures;

j. End -to-end production process for mesh products, including the purchasing, testing and chemical composition of raw material, the extrusion of continuous filament, winding, weaving, knitting, scouring, and/or annealing;

k. Inspecting finished mesh products for surface effects and/or variations in the finished products;

l. Measuring process variables, including temperature effects at the extrusion die, water content of the polymer, the finish of the tool and/or residual process materials that have not been completely removed through scouring;

m. Measuring polypropylene variables, including tacticity, presence of extrusion processing aids, monomers, dimers and/or residual catalyst;

n. Implementing and maintaining any manufacturing and distribution process tracking technologies employed by Ethicon LLC, including but not limited to technologies such as RFID and barcodes and the means of collection, retention and integration of these data through the product lifecycle;

o. Installing, inspecting, maintaining, and operating equipment used to produce mesh products, including, but not limited to laser cutting equipment and mechanical cutting equipment used in the production of mesh products or polypropylene sutures;

p. Process flow for incoming and outgoing raw materials, partially finished materials, and final products for the production of mesh products and polypropylene sutures;

q. The substantive preparation, printing, and placement of package inserts, product packaging, IFUs and other labeling for your mesh products (both U.S. and foreign), including the specific dates of use for each such items and any changes thereto;

r. The substantive preparation and approval of any manufacturing process changes regarding your mesh products, including the specific dates and reasons for each change;

s. Any investigation, evaluation and determination as to whether there is an association between manufacturing defects/problems/errors related to your mesh products and any adverse event experienced by a patient who was provided your mesh products;

t. Any investigation, evaluation and determination as to whether there is an association or causal connection between your mesh materials, component parts or products and any adverse event or injuries;

u. Any documents which pertain to or discuss personal injury litigation concerning your mesh products, including but not limited to documentation of litigation holds;

v. The maintenance of Ethicon LLC's finances, budgets and expenditures related to its mesh products from the date first started developing and manufacturing its mesh products until the present;

w. The interaction and communication internally or with any outside contractors, vendors or consultants regarding the manufacturing, engineering, distribution, regulatory compliance, or the safety of your mesh products for use by humans, from the date Ethicon, LLC first started developing and manufacturing mesh products until the present;

x. The interaction and communication internally or with any outside vendors regarding the safety of the use of the raw materials used in the manufacturing of your mesh products and polypropylene sutures, from the date Ethicon, LLC first started developing, packaging and/or manufacturing mesh products until the present;

y. Any internal communications or external communication with vendors, suppliers, contractors or consultants related to whether polypropylene is safe for use in your mesh products or polypropylene sutures;

z. The Corrective and Preventative Action Plan ("CAPA") relating to failure to properly maintain documents necessary for regulatory or litigation purposes;

aa. Any material safety data sheets for polypropylene or product safety data sheets for polypropylene in your possession from the date you first started manufacturing your mesh products;

bb. Any material safety data sheets or product safety sheets for the raw materials or component parts of your mesh products and polypropylene sutures from the date you first started manufacturing your mesh products;

cc. The Corrective and Preventative Action Plan ("CAPA") relating to failure of Prolene Mesh not being packaged (folded) as specified in the Process Specification for Packaging of Mesh Product;

dd. The Corrective and Preventative Action Plan ("CAPA") relating to Gynemesh non-absorbable Prolene Soft mesh not being properly sealed as well as evaluating units for packaging integrity;

ee. The existence and handling of manufacturing related complaints and non-conformance reports regarding your mesh products and sutures;

ff. The method of supply and the identity of the suppliers of any and all materials or component parts of your mesh products and polypropylene sutures;

gg. End-to-end production process for your mesh products, including the purchasing, testing and chemical composition of raw material, the extrusion of your mesh products;

hh. The existence and handling of manufacturing related complaints and non-conformance reports regarding your mesh products.

ii. Documentation of Investigations of causes of manufacturing nonconformities and corrective and preventative actions ("CAPA");

jj. The auditing of the conduct of the company and its officers and employees in connection with the manufacture, distribution, testing and quality of mesh products from the date Ethicon, LLC first started developing mesh products until the present;

kk. Ethicon LLC's quality manual, quality policy, written procedures for management review, quality audits and quality plan and management review of the same;

ll. Manufacturing standards for measuring space between pores of mesh products as well as evaluation and testing of the space between the pores;

mm. Product that did not meet product specifications as well as the destruction or disposal of such product including records of the product;

nn. The suppliers of the polypropylene mesh and resin, including any contracts with any third parties about or relating to the supply of polypropylene mesh and resin; and

oo. The existence of and terms of all hold harmless agreements or indemnification agreements between Ethicon LLC and its vendors, suppliers, consultants, distributors or other manufacturers of mesh products;

pp. The inspection, maintenance and sterilization schedule for any equipment used by Ethicon LLC in the production of mesh products or polypropylene sutures, including the ownership of such equipment and the identity of any third parties contracted to perform inspection, maintenance, or sterilization of said equipment;

qq. The inspection, maintenance, and sterilization schedule for any facilities used by Ethicon LLC in the production of mesh products or polypropylene sutures including the ownership of said facilities and any third parties contacted to perform inspection, maintenance or sterilization of said equipment;

rr. Policies and procedures of Ethicon LLC regarding the measurement and maintenance of temperature and humidity within the facilities used in the manufacture, storage, or transportation of mesh products, polypropylene sutures, or raw materials for mesh products and polypropylene sutures.

2. The processes and procedures used by Ethicon, LLC in connection with processing of non-conformance reports, including the identification of policy manuals, SOPs, and safety manuals.

3. The process and procedures for storing, testing and/or analyzing mesh products that have been returned to Ethicon, LLC due to complaints of malfunction or complications and the location of any and all such storage facilities.

III. OUTSIDE CONTRACTORS/CONSULTANTS

1. All persons or entities that Ethicon, LLC (including the name, employer or the corporate entity the person is associated with, the time period in which the relationship existed, the title, role, function of the individual or entity, and a general description of the nature of the consultation or discussion) consulted with, paid or retained concerning your mesh products from the date Ethicon, LLC first started developing mesh products until the present. Areas of inquiry related to the identity of these consultants will include but will not be limited to the following:

a. Ensuring and/or evaluating compliance with laws and regulations regarding product manufacturing;

b. Ensuring and or evaluating compliance with quality manufacturing procedures and policies, included but not limited to auditing of procedures such as ISO 9000 and any similar procedures;

c. Any consultants involved in responding to any perceived deficiencies to Ethicon LLC's processes or manufacturing, including Corrective and Preventative Actions, (CAPA's) Product Quality Issues (PQI's), or non-conformance issues or problems;

d. Any consultants involved with testing, maintenance, repair, setup and operation of plant equipment;

e. Any scientific, manufacturing, and engineering consultants;

f. Any product testing consultants;

g. Any machine testing consultants;

h. Any consultants or contractors involved with the supply of mesh, the type of mesh to be used in the mesh products, or the safety of the mesh to be used in the r mesh products.

2. Ethicon LLC's third party consultants or entities retained for Manufacturing, Engineering, Product Testing, Auditing, and the nature of the work done by those consultants and the time periods during which they were retained from the date Ethicon LLC first started developing mesh products until the present.

VI. REGULATORY COMMUNICATIONS

1. All interactions between Ethicon LLC and the FDA or other regulatory bodies in the United States concerning Ethicon LLC's manufacturing or distribution of mesh products or component parts making up such mesh products, including the location, storage and organization of any and all documents that relate to or reflect the same.

2. Communications between Ethicon LLC and the FDA or other federal government entity or agency regarding the manufacturing of mesh products.

EXHIBIT "B"

DOCUMENT REQUESTS

Please produce:

1. All documents relied upon by the deponent in preparing for this deposition.

2. All documents reflecting correspondence between the FDA and Ethicon LLC regarding mesh products or facilities and procedures involved in the manufacture of mesh products or polypropylene sutures.

3. All current and former product specifications for mesh products and polypropylene sutures including draft copies.

4. Ethicon LLC's quality manual, quality policy, written procedures for management review, quality audits and quality plan as well as minutes and notes management review meetings regarding these documents.

5. Any documents indicating or discussing deviation from product specifications, including but not limited to: fraying, bunching, curling, degradation, fading, crumbling, folding, toxicity or sizing of mesh products or polypropylene sutures.

6. Records of mesh product that was rejected and destroyed or otherwise disposed for not meeting product specifications.

7. All agreements between Ethicon LLC and third parties or consultants related to the supply of mesh products or polypropylene resin for use in humans.

8. All documents related to whether the use of polypropylene mesh, sutures, or resin is safe for use in humans.

9. Any material safety data sheets for polypropylene or product safety data sheets for polypropylene in your possession from the date you first started manufacturing your mesh products or polypropylene sutures.

10. Any material safety data sheets or product safety sheets for the raw materials or component parts of your mesh products and polypropylene sutures from the date you first started manufacturing your mesh products.

11. All communications with any vendors, suppliers or other third parties related to the supply of materials or component parts for the manufacture of the mesh products.

12. All documentation regarding Corrective and Preventative Actions ("CAPAs") and Product Quality Issues ("PQIs") regarding the mesh products manufactured,

handled, or processed by you, including but not limited to memoranda, draft, and final reports of such actions and issues and all communications between Ethicon LLC and other Johnson & Johnson entities and third parties regarding such actions and issues.

13. Any records reflecting the inspection, maintenance or sterilization for any equipment or facilities used by Ethicon LLC in the production of mesh products or polypropylene sutures, including the ownership of such equipment and communications with any third parties contracted to perform inspection, maintenance, or sterilization of said equipment or facilities.
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14. Any records reflecting the measurement and maintenance of temperature and humidity within the facilities utilized by Ethicon LLC in the manufacture, storage, or transportation of mesh products, polypropylene sutures, and polypropylene resin.

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THIS DOCUMENT RELATES TO ALL CASES	**JOSEPH R. GOODWIN** **U.S. DISTRICT JUDGE**

CERTIFICATE OF SERVICE

I hereby certify that on May 30, 2014, I electronically filed the foregoing document with the Clerk of the court using CM/ECF system which will send notification of such filing to the CM/ECF participants registered to receive service in this MDL.

PLAINTIFFS' CO-LEAD COUNSEL

By: ____/s/Thomas P. Cartmell_____

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